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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

7 CFR Part 305

[Docket No. APHIS-2013-0081]

RIN 0579-AD90

Standardizing Phytosanitary Treatment Regulations: Approval of Cold Treatment and Irradiation Facilities; Cold Treatment Schedules; Establishment of Fumigation and Cold Treatment Compliance Agreements

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Proposed rule.

SUMMARY: We are proposing to amend the phytosanitary treatment regulations to establish generic criteria that would allow for the approval of new cold treatment facilities in the Southern and Western States of the United States. These criteria, if met, would allow us to approve new cold treatment facilities without rulemaking and facilitate the importation of fruit requiring cold treatment while continuing to provide protection against the introduction of pests of concern into the United States. We are also proposing to amend the fruit cutting and inspection requirements in the cold treatment regulations in order to expand cutting and inspection to commodities that have been treated for a wider variety of pests of concern. This action would provide for a greater degree of phytosanitary protection. We are also proposing to add requirements concerning the establishment of compliance agreements for all entities that operate fumigation facilities. Finally, we are proposing to harmonize language concerning State compliance with facility establishment and parameters for the movement of consignments from the port of entry or points

of origin in the United States to the treatment facility in the irradiation treatment regulations with proposed language in the cold treatment regulations. These actions would serve to codify and make enforceable existing procedures concerning compliance agreements for these facilities.

DATES: We will consider all comments that we receive on or before [Insert date 60 days after date of publication in the Federal Register].

ADDRESSES: You may submit comments by either of the following methods:

- Federal eRulemaking Portal: Go to <http://www.regulations.gov/#!docketDetail;D=APHIS-2013-0081>.
- Postal Mail/Commercial Delivery: Send your comment to Docket No. APHIS-2013-0081, Regulatory Analysis and Development, PPD, APHIS, Station 3A-03.8, 4700 River Road Unit 118, Riverdale, MD 20737-1238.

Supporting documents and any comments we receive on this docket may be viewed at <http://www.regulations.gov/#!docketDetail;D=APHIS-2013-0081> or in our reading room, which is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799-7039 before coming.

FOR FURTHER INFORMATION CONTACT: Mr. David B. Lamb, Senior Regulatory Policy Specialist, IRM, PPQ, APHIS, 4700 River Road Unit 133, Riverdale, MD 20737-1231; (301) 851-2103.

SUPPLEMENTARY INFORMATION:

Background

The phytosanitary treatments regulations in 7 CFR part 305 set out general requirements for certifying or approving treatment facilities and for performing treatments listed in the Plant Protection and Quarantine (PPQ) Treatment Manual¹ for fruits, vegetables, and other articles to prevent the introduction or dissemination of plant pests or noxious weeds into or through the United States. Within part 305, § 305.6 (referred to below as the regulations) sets out requirements for treatment procedures, monitoring, facilities, and enclosures needed for performing sustained refrigeration (cold treatment) sufficient to kill certain insect pests associated with imported fruits and vegetables and with regulated articles moved interstate from quarantined areas within the United States. Under the regulations, all domestic facilities used to provide cold treatment for these articles must operate under a compliance agreement with the Animal and Plant Health Inspection Service (APHIS) and be certified as capable of delivering required cold treatment and handling articles to prevent reinfestation of treated articles. An inspector² monitors all domestic treatments. The regulations require safeguards to prevent the escape of pests during transportation to and while at the facility. These include, but are not limited to, inspections, precooling, and physical separation of untreated and treated articles. The facility must maintain records of all treatments and must periodically be recertified. These

¹ The PPQ Treatment Manual is available at (http://www.aphis.usda.gov/import_export/plants/manuals/ports/downloads/treatment.pdf).

² Section 305.1 defines an inspector as “Any individual authorized by the Administrator of APHIS or the Commissioner of Customs and Border Protection, Department of Homeland Security, to enforce the regulations in this part.”

conditions have allowed for the safe, effective treatment of many different kinds of articles, as is demonstrated by the track record of cold treatment facilities currently operating in the United States and other countries.

Cold Treatment in Southern and Western States

In § 305.6, paragraph (b) allows cold treatment facilities to be located in the area north of 39° latitude and east of 104° longitude. When the cold treatment regulations were established, areas outside of these coordinates were identified as having conditions favorable for the establishment of exotic fruit flies. The location restrictions served as an additional safeguard against the possibility that fruit flies could escape from imported articles prior to treatment and become established in the United States.

Although the regulations initially did not allow cold treatment facilities to be located in Southern and Western States, APHIS periodically received requests for exemptions. In response to these requests, APHIS conducted site-specific evaluations for these locations and determined that regulated articles can be safely transported to, handled in, and treated by specific cold treatment facilities outside of the areas established by the regulations under special conditions to mitigate the possible escape of pests of concern. Over the years, APHIS has amended its regulations to allow cold treatment facilities to be located at the maritime ports of Wilmington, NC; Seattle, WA; Corpus Christi, TX; and Gulfport, MS; Seattle-Tacoma International Airport, Seattle, WA; Hartsfield-Atlanta International Airport, Atlanta, GA; and, most recently, MidAmerica St. Louis Airport, Mascoutah, IL.

In addition to those requests, certain importers of fruits and vegetables have shown considerable interest in locating cold treatment facilities in places that are not currently allowed under the regulations (e.g., Miami and Port Everglades, FL, and Savannah, GA).

Proposed Changes to the Regulations Governing Cold Treatment Facilities in Southern and Western States

In anticipation of future requests to locate additional cold treatment facilities in the Southern and Western States of the United States, we are proposing to establish generic phytosanitary criteria that would replace the current location-specific criteria for cold treatment facilities at the ports mentioned previously and would also apply to new cold treatment facilities in the Southern and Western States of the United States. The proposed criteria are similar to those successfully used for the approval of new irradiation facilities in the Southern United States found in § 305.9 of the regulations, as untreated fruit moving to irradiation facilities in those States presents the same pest risks as untreated fruit moving to cold treatment facilities. We would not require currently approved cold treatment facilities in Southern and Western States to immediately meet the proposed generic criteria since the specific requirements presently in place for each facility would continue to provide adequate phytosanitary protection. Nevertheless, we would require currently approved facilities to meet the new generic requirements as each comes up to renew its required recertification, which takes place at 3 year intervals or at other times as determined by APHIS based on treatments performed, commodities handled, and operations conducted at the facility.

All cold treatment facilities in the Southern and Western States would be required to meet the current criteria for cold treatment facilities north of 39° latitude and east of 104° longitude, in addition to the proposed generic criteria. These generic criteria would be supplemented as necessary by additional measures, which would be described in a compliance agreement (discussed below), based on pests of concern associated with specific regulated articles to be treated at the facility and the location of the specific facility. Facilities that meet these

requirements could then be approved for the treatment of regulated articles that are imported, moved interstate from Hawaii or U.S. territories, or moved interstate from areas quarantined for certain pests of concern.

Using APHIS-approved cold treatment facilities located in the United States, rather than those located outside of the United States, to treat imported articles offers the advantage of greater ease of monitoring treatment. Using generic criteria, rather than site by site approval, for future cold treatment facilities located in Southern and Western States would make explicit our criteria for approving these facilities while eliminating the need to undertake rulemaking in order to approve new facilities.

To support this action, we have prepared a treatment evaluation document (TED) entitled “Phytosanitary Criteria for Establishing Locations for Cold Treatment Facilities in Areas of the United States Currently Not Allowed.” Copies of the TED may be obtained from the person listed under FOR FURTHER INFORMATION CONTACT and may be viewed on the Internet on the Regulations.gov Web site or in our reading room (see ADDRESSES above for instructions for accessing Regulations.gov and the location and hours of the reading room). In the TED, we concluded that the pest risks presented by cold treatment facilities in the Southern and Western States can be adequately managed through the use of special conditions to mitigate the possible escape of pests of concern.

We are therefore proposing to amend the regulations by replacing the current specific criteria for cold treatment facilities at the maritime ports of Wilmington, NC; Seattle, WA; Corpus Christi, TX; and Gulfport, MS; Seattle-Tacoma International Airport, Seattle, WA; MidAmerica St. Louis Airport, Mascoutah, IL; and Hartsfield-Atlanta International Airport, Atlanta, GA, in § 305.6 with generic phytosanitary criteria for any cold treatment facility in a

Southern or Western State. The proposed generic criteria would have to be followed in addition to the current requirements that apply to all cold treatment facilities. The proposed generic criteria for new facilities in the Southern and Western States are based on the current conditions for allowing cold treatment facilities at the maritime ports of Wilmington, NC; Seattle, WA; Corpus Christi, TX; and Gulfport, MS; Seattle-Tacoma International Airport, Seattle, WA; MidAmerica St. Louis Airport, Mascoutah, IL; and Hartsfield-Atlanta International Airport, Atlanta, GA.

In proposed paragraph (b)(1)(i) of § 305.6, we would require that prospective facility operators submit a detailed layout of the facility site and its location to APHIS. APHIS would evaluate plant health risks based on the proposed location and layout of the facility site before a facility is approved. APHIS would only approve a proposed facility if the Administrator determines that regulated articles can be safely transported to the facility from the port of entry or points of origin in the United States. Proposed paragraph (b)(1)(ii) of § 305.6 provides that the State government of the Southern or Western State in which the facility would be located would also have to concur in writing with the location of the cold treatment facility; if it does not concur, the State government must provide a written explanation of concern based on pest risks. In instances where the State government does not concur with the proposed facility location, and provides a written explanation of concern based on pest risks, then APHIS and the State would need to agree on a strategy to resolve such risks before APHIS approved the facility. If the State does not provide a written explanation of concern based on pest risks, then State concurrence will not be required before APHIS approves the facility location.

Under this proposal, paragraphs (b)(1)(iii) and (b)(1)(iv) of § 305.6 would provide, respectively, that untreated articles may not be removed from their packaging prior to treatment under any circumstances, and that facilities must have contingency plans, approved by APHIS, for safely destroying or disposing of regulated articles if the facility were unable to properly treat a shipment. Alternatively, facilities could be approved to apply alternative treatments, if available, such as fumigation with methyl bromide or irradiation.

Proposed paragraph (b)(1)(v) of § 305.6 would allow a cold treatment facility to treat only those articles that are approved by APHIS for treatment at that facility. If, during the approval process for regulated articles, APHIS determines that additional safeguards (such as trapping for specific pests using specific lures, inspection for any pests of concern not mitigated by cold treatment or to monitor pest population in the consignment, or applying required treatments in addition to cold treatment) are deemed necessary during transport or while at a specific cold treatment facility, the compliance agreement for the facility would be amended accordingly.

Under proposed paragraph (b)(1)(vi) of § 305.6, APHIS, the importer, and the cold treatment facility would need to agree on arrangements for treatment before the departure of a consignment from its country of origin or point of origin in the United States. This would ensure that untreated shipments of regulated articles arriving at the facility would not have to wait for an extended period of time for cold treatment. The expeditious treatment of the articles would minimize the risk of pests of concern maturing in fruits, vegetables, or other articles. In addition, we are proposing that APHIS and the cold treatment facility would have to agree in advance about all parameters, such as time, routing, and conveyance, by which every consignment would move from the port of entry or points of origin in the United States to the cold treatment facility.

In most instances, this would be determined by establishing the shortest route between the port of entry or points of origin in the United States and the cold treatment facility that does not include an area that contains host material for pests of concern during the time of year that the host material is most abundant in the region. This route would then be used at all times of the year, since an area that is free of host material during the time of year that it is most abundantly grown, would be unlikely to grow host material at any other time of year. This predetermined route would reduce the amount of time that a shipment would have to wait before undergoing cold treatment and would reduce the risk that any pests of concern in the shipments would come into contact with host material en route to the cold treatment facility. If APHIS and the cold treatment facility cannot reach agreement in advance on all parameters by which consignments would move from the port of entry or points of origin in the United States then no consignments may be moved to that facility until an agreement has been reached.

We are also proposing to require in paragraph (b)(1)(vii) of § 305.6 that the conveyance transporting the regulated article to the cold treatment facility would need to be refrigerated using motorized refrigeration equipment to a temperature that would minimize the mobility of the pests of concern for the article. Fruits and vegetables requiring cold treatment are typically transported in refrigerated conveyances in order to preserve freshness of the commodity and prevent development of toxins that may affect their flavor.

Proposed paragraph (b)(1)(viii) of § 305.6 would stipulate that the cold treatment facility would be required to apply all required post-treatment safeguards as required by the compliance agreement to provide phytosanitary protection (e.g., larger consignments broken up into smaller boxes following treatment and those treated articles subsequently packaged in pest-proof containers per an agreement between the treatment facility and the importer) before releasing the

articles to the importer or the importer's designated representative or before moving the articles interstate. Paragraph (b)(1)(ix) would require the facility to remain locked when not in operation. These requirements are intended to minimize the risk of cross-contamination between treated and untreated articles and to prevent unauthorized persons access to the facility, which may result in the unintended entry of pests of concern.

The current regulations for cold treatment facilities at the maritime ports of Seattle, WA; Corpus Christi, TX; and Gulfport, MS; Seattle-Tacoma International Airport, Seattle, WA; and Hartsfield-Atlanta International Airport, Atlanta, GA, require blacklight or sticky paper to be used within the cold treatment facility and other trapping methods to be used within the 4 square miles surrounding the facility. Proposed paragraph (b)(1)(x) of § 305.6 requires, in addition, that the facility maintain and provide APHIS an updated map identifying places where horticultural or other crops are grown within 4 square miles of the facility. APHIS will use this information to determine if any host material of concern is present. To help prevent establishment of pests in the unlikely event that they escape despite the required precautions, the presence of any host material within 4 square miles of the facility would then necessitate specific trapping or other pest monitoring activities to help prevent establishment of any escaped pests of concern, which would be funded by the facility and described in the compliance agreement. All trapping and pest monitoring activities would need to be approved by APHIS.

The cold treatment facility would also need to have a pest management plan within the facility, which would cover such topics as monitoring for pests in storage and treatment areas and the actions to be taken in the event of the detection of pests within the facility. Cold treatment facilities would also be required to comply with any additional requirements that APHIS might require for a particular facility based on local conditions and any other risk factors

of concern. This could include inspection for certain pests for which cold treatment is not an approved treatment, such as mites and scales. Proposed paragraph (b)(1)(xi) of § 305.6 would require that facilities comply with any additional APHIS requirements including, but not limited to, the use of pest-proof packaging and container seals. Such additional requirements would be contained in a compliance agreement. Compliance agreements are required for all facilities in paragraph (f) of § 305.6, which we are proposing to amend as detailed below under the heading “Cold Treatment Facilities in All the United States.”

We also propose to add language specifying the way in which domestically produced fruit would be safeguarded when moving interstate from areas within the United States that are quarantined for fruit flies. In proposed paragraph (b)(2) of § 305.6, we would stipulate that, for articles that are moved interstate from areas quarantined for fruit flies, cold treatment facilities would be permitted to be located within or outside of the quarantined area. If the articles are treated outside the quarantined area, they would have to be accompanied to the facility by a limited permit issued in accordance with 7 CFR 301.32-5(b) of our fruit fly regulations and must be moved in accordance with any safeguards determined appropriate by APHIS. These additions are necessary because the current cold treatment regulations do not address interstate movement and this addition would serve to clarify our requirements.

Cold Treatment Facilities in All the United States

In paragraph (a) of § 305.6, we are proposing to expand our requirements for initial facility certification and recertification. A prospective facility would only be certified if the Administrator determines that the location of that facility is operationally feasible insofar as the Federal agencies involved in its operation and oversight have adequate resources to conduct the necessary operations at the facility, that the pest risks can be managed at that location, and that

the facility meets all criteria for approval. Facility recertification would continue to be required at 3 year intervals or at other times as determined by APHIS based on treatments performed, commodities handled, and operations conducted at the facility.

Currently, as part of the approval process for cold treatment facilities, APHIS considers whether a proposed cold treatment facility is located within the local commuting area for APHIS employees so that they will be able to perform the oversight and monitoring activities required by § 305.6. When imported articles are to be treated at a facility, APHIS also considers whether the facility is located within an area over which the U.S. Department of Homeland Security (DHS)³ has customs authority for enforcement purposes. We are proposing to amend paragraph (e) of § 305.6, which contains requirements for monitoring and interagency agreements for cold treatment facilities, to require all cold treatment facilities to be located within the local commuting area for APHIS employees⁴ for oversight and monitoring purposes. For facilities treating imported articles, we are also proposing that the location of the facility would have to be within an area over which DHS has customs authority for enforcement purposes.

The regulations in § 305.6(d)(15) currently stipulate that an inspector will sample and cut fruit from consignments that have been cold treated for Mediterranean fruit fly (Medfly) in order to monitor treatment effectiveness. We are proposing to expand the fruit cutting and inspection

³ The U.S. Department of Homeland Security is assigned authority to accept entries of merchandise, to collect duties, and to enforce the provisions of the customs and navigation laws in force.

⁴ Commuting area would be determined by contacting the local APHIS Plant Protection and Quarantine office, State Plant Health Director, located in each State, Eastern Regional Office, or Western Regional Office.

requirements in order to state that consignments treated for other fruit flies and pests of concern may be subject to sampling and cutting. This would create an extra level of phytosanitary security for cold treated shipments.

If the national plant protection organization cuts and inspects the commodity in the exporting country as part of a biometric sampling protocol that we have approved, however, we are proposing that we may waive this requirement. In such instances, inspection and cutting would be duplicative.

Paragraph (f) of § 305.6 currently requires that cold treatment facilities located in the United States must enter into a compliance agreement with APHIS. These compliance agreements set out requirements for equipment, temperature, circulation, and other operational requirements for performing cold treatment to ensure that treatments are administered properly. They also allow for inspection by APHIS in order to monitor compliance with those requirements. Paragraph (g) contains requirements for facilities located outside the United States, which may only operate under a bilateral workplan. A bilateral workplan may contain some of the same requirements as a domestic compliance agreement, with the potential addition of trust fund agreement information regarding payment of the salaries and expenses of APHIS employees on site. We are proposing to combine these requirements into a single paragraph that would set out the requirements that both domestic and foreign cold treatment facilities and importers would have to meet in order to enter into a compliance agreement with APHIS. We are also proposing to add language regarding compliance agreements required in association with articles moved interstate from Hawaii and the U.S. territories. These requirements are consistent with those required for importers shipping articles to irradiation facilities located in the southern United States and are necessary to ensure that consignments of fruits or vegetables are not

diverted to any destination other than an approved treatment facility, to prevent escape of plant pests from the articles to be treated during their transit from the port of first arrival into the United States to the approved cold treatment facility, and to ensure that APHIS is aware of the time, route, and conveyance by which consignments will move to the treatment facility.

Fumigation Treatment and Compliance Agreements

We are proposing to add a section to the regulations concerning fumigation treatment found in § 305.5 to provide that both domestic and foreign fumigation treatment facilities and importers enter into a compliance agreement with APHIS, and agree to comply with any requirements deemed necessary by the Administrator. Although we currently enter into compliance agreements with domestic chemical treatment facilities and have done so for more than 20 years, the addition of a requirement for compliance agreements to the fumigation treatment regulations will add a degree of enforceability to the terms of those agreements in addition to codifying our existing practices.

We are also proposing to add a requirement concerning establishment of a compliance agreement, or an equivalent agreement such as a workplan agreement, for those fumigation treatment facilities located outside the United States. Such facilities had not been previously required to sign such an agreement to treat articles imported into the United States under the fumigation treatment regulations. The proposed requirements would be identical to those found in the sections of the treatment regulations concerning cold treatment and heat treatment, and would be added in a new paragraph (c) in § 305.5.

Irradiation Treatment and State and Facility Compliance

We are proposing to harmonize the language concerning State compliance with irradiation treatment facility establishment and facility agreements found in § 305.9 with the proposed language concerning this compliance in the cold treatment regulations.

Section 305.9(a)(1)(ii) states that the government of the State in which the facility is to be located must concur in writing with the establishment of the facility or, if it does not concur, must provide a written explanation of concern based on pest risks. In instances where the State government does not concur with the proposed facility location, APHIS and the State will agree on a strategy to resolve the pest risk concerns prior to APHIS approval. We would add that, if the State does not provide a written explanation of concern based on pest risks, then State concurrence will not be required before APHIS approves the facility location.

Section 305.9(a)(1)(vi) states that APHIS and the irradiation treatment facility must agree on all parameters, such as time, routing, and conveyance, by which the consignment will move from the port of entry or points of origin in the United States to the treatment facility. We are proposing to clarify that if APHIS and the facility cannot reach agreement in advance on these parameters then no consignments may be moved to that facility until an agreement has been reached.

Definitions

We are also proposing to add a definition for “treatment facility” as follows to the regulations in § 305.1: “Any APHIS-certified place, warehouse, or approved enclosure where a treatment is conducted to mitigate a plant pest.” This is intended to provide clarity and guidance in the regulations as the term is included in the proposed additions to the regulations.

Treatment Schedules

Finally, the current regulations in § 305.2, paragraph (b), state that approved treatment schedules are set out in the PPQ Treatment Manual. Section 305.3 sets forth a process for adding, revising, or removing treatment schedules in the PPQ Treatment Manual. Paragraph (a)(1) provides that removal of a treatment schedule is subject to public comment.

We are proposing to remove a cold treatment schedule from the PPQ Treatment Manual. Treatment schedule T107-f was authorized for use on shipments of Ya pears (Pyrus x bretschneideri) from APHIS-authorized areas within Shandong Province, China, in order to provide phytosanitary protection against the Oriental fruit fly (Bactrocera dorsalis). Based on Oriental fruit fly trapping results and climatological and biological considerations, we have determined that cold treatment of Ya pears is no longer necessary and are therefore proposing to remove the treatment schedule. All other requirements regarding the importation of Ya pears would remain in place.

Executive Order 12866 and Regulatory Flexibility Act

This proposed rule has been determined to be not significant for the purposes of Executive Order 12866 and, therefore, has not been reviewed by the Office of Management and Budget.

In accordance with the Regulatory Flexibility Act, we have analyzed the potential economic effects of this action on small entities. The analysis is summarized below. Copies of the full analysis are available on the Regulations.gov Web site (see ADDRESSES above for instructions for accessing Regulations.gov) or by contacting the person listed under FOR FURTHER INFORMATION CONTACT.

We are proposing to establish general criteria for new cold treatment facilities in the Southern and Western United States. These general criteria would be supplemented as necessary by additional measures, which would be described in the facility's compliance agreement, based on pests of concern associated with specific regulated articles to be treated at the facility and the location of the specific facility.

We do not anticipate that the proposed rule would have an economic impact, since it would simply set forth the general criteria, not approve any new facilities.

Under these circumstances, the Administrator of the Animal and Plant Health Inspection Service has determined that this action would not have a significant economic impact on a substantial number of small entities.

Executive Order 12988

This proposed rule has been reviewed under Executive Order 12988, Civil Justice Reform. If this proposed rule is adopted: (1) All State and local laws and regulations that are inconsistent with this rule will be preempted; (2) no retroactive effect will be given to this rule; and (3) administrative proceedings will not be required before parties may file suit in court challenging this rule.

Paperwork Reduction Act

In accordance with section 3507(d) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.), the information collection or recordkeeping requirements included in this proposed rule have been submitted for approval to the Office of Management and Budget (OMB). Please send written comments to the Office of Information and Regulatory Affairs, OMB, Attention: Desk Officer for APHIS, Washington, DC 20503. Please state that your comments refer to Docket No. APHIS-2013-0081. Please send a copy of your comments to: (1) APHIS, using one of the methods described under ADDRESSES at the beginning of this document, and (2) Clearance Officer, OCIO, USDA, room 404-W, 14th Street and Independence Avenue SW., Washington, DC 20250.

APHIS is proposing to amend the phytosanitary treatment regulations to establish generic criteria that would allow for the approval of new cold treatment facilities in the Southern and

Western States of the United States. These criteria, if met, would allow APHIS to approve new cold treatment facilities without rulemaking and facilitate the importation of fruit requiring cold treatment while continuing to provide protection against the introduction of pests of concern into the United States. APHIS is also proposing to amend the fruit cutting and inspection requirements in the cold treatment regulations in order to expand cutting and inspection to commodities that have been treated for a wider variety of pests of concern. This action would provide for a greater degree of phytosanitary protection. Finally, APHIS is proposing to add requirements concerning the establishment of compliance agreements for those entities that operate fumigation facilities. This action would serve to codify and make enforceable existing procedures concerning compliance agreements for these facilities.

Implementing this rule will require the completion of compliance agreements, facility certification, detailed layouts of facilities and maps of the surrounding areas, State concurrence letters, limited permits, and contingency plans.

We are soliciting comments from the public (as well as affected agencies) concerning our proposed information collection and recordkeeping requirements. These comments will help us:

(1) Evaluate whether the proposed information collection is necessary for the proper performance of our agency's functions, including whether the information will have practical utility;

(2) Evaluate the accuracy of our estimate of the burden of the proposed information collection, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the information collection on those who are to respond (such as through the use of appropriate automated, electronic, mechanical, or other technological

collection techniques or other forms of information technology; e.g., permitting electronic submission of responses).

Estimate of burden: Public reporting burden for this collection of information is estimated to average 0.5 hours per response.

Respondents: NPPO, facility operators, importers, and State governments.

Estimated annual number of respondents: 15.

Estimated annual number of responses per respondent: 3.

Estimated annual number of responses: 42.

Estimated total annual burden on respondents: 21 hours. (Due to averaging, the total annual burden hours may not equal the product of the annual number of responses multiplied by the reporting burden per response.)

Copies of this information collection can be obtained from Ms. Kimberly Hardy, APHIS' Information Collection Coordinator, at (301) 851-2727.

E-Government Act Compliance

The Animal and Plant Health Inspection Service is committed to compliance with the E-Government Act to promote the use of the Internet and other information technologies, to provide increased opportunities for citizen access to Government information and services, and for other purposes. For information pertinent to E-Government Act compliance related to this proposed rule, please contact Ms. Kimberly Hardy, APHIS' Information Collection Coordinator, at (301) 851-2727.

List of Subjects in 7 CFR Part 305

Irradiation, Phytosanitary treatment, Plant diseases and pests, Quarantine, Reporting and recordkeeping requirements.

Accordingly, we propose to amend 7 CFR part 305 as follows:

PART 305—PHYTOSANITARY TREATMENTS

1. The authority citation for part 305 continues to read as follows:

Authority: 7 U.S.C. 7701-7772 and 7781-7786; 21 U.S.C. 136 and 136a; 7 CFR 2.22, 2.80, and 371.3.

2. Section 305.1 is amended by adding, in alphabetical order, a definition for treatment facility to read as follows:

§ 305.1 Definitions.

* * * * *

Treatment facility. Any APHIS-certified place, warehouse, or approved enclosure where a treatment is conducted to mitigate a plant pest.

* * * * *

3. Section 305.5 is amended by redesignating paragraph (c) as paragraph (d) and adding a new paragraph (c).

The addition reads as follows:

§ 305.5 Chemical treatment requirements.

* * * * *

(c) Compliance agreements. Any person who conducts a fumigation or operates a facility where fumigation is conducted for phytosanitary purposes must sign a compliance agreement with APHIS.

(1) Fumigation treatment facilities treating imported articles. (i) Compliance agreements with importers and facility operators for fumigation in the United States. If fumigation treatment of imported articles is conducted in the United States, both the importer and the fumigation treatment facility operator or the person who conducts fumigation must sign compliance agreements with APHIS. In the importer compliance agreement, the importer must agree to comply with any additional requirements found necessary by APHIS to ensure the shipment is not diverted to a destination other than an approved treatment facility and to prevent escape of plant pests from the articles to be treated during their transit from the port of first arrival to the fumigation treatment facility in the United States. In the facility compliance agreement, the fumigation facility operator or the person who conducts fumigation must agree to comply with the requirements of this section and any additional requirements found necessary by APHIS to prevent the escape of any pests of concern that may be associated with the articles to be treated.

(ii) Compliance agreements with fumigation treatment facilities outside the United States. If fumigation treatment of imported articles is conducted outside the United States, the fumigation treatment facility operator or the person who conducts the fumigation must sign a compliance agreement or an equivalent agreement with APHIS and the national plant protection organization (NPPO) of the country in which the facility is located. In this agreement, the fumigation treatment facility operator or person conducting the fumigation must agree to comply with the requirements of this section, and the NPPO of the country in which the facility is located must agree to monitor that compliance and to inform the Administrator of any noncompliance.

(2) Fumigation treatment facilities treating articles moved interstate from Hawaii and U.S. territories. Fumigation treatment facilities treating articles moved interstate from Hawaii and U.S. territories must complete a compliance agreement with APHIS as provided in § 318.13-3(d) of this chapter.

(3) Fumigation treatment facilities treating articles moved interstate from areas quarantined for fruit flies. Fumigation treatment facilities treating articles moved interstate from areas quarantined for fruit flies must complete a compliance agreement with APHIS as provided in § 301.32-6 of this chapter.

(4) Fumigation treatment facilities treating articles moved interstate from areas quarantined for Asian citrus psyllid. Fumigation treatment facilities treating articles moved interstate from areas quarantined only for Asian citrus psyllid, and not for citrus greening, must complete a compliance agreement with APHIS as provided in § 301.76-8 of this chapter.

* * * * *

4. Section 305.6 is amended as follows:

a. In the introductory text of paragraph (a), by adding two new sentences before the last sentence.

b. By redesignating paragraph (a)(2) as paragraph (a)(3).

c. By adding new paragraph (a)(2).

d. By revising paragraph (b).

e. By revising paragraph (d)(15).

f. In paragraph (e), by adding two new sentences after the last sentence.

g. By revising paragraph (f).

h. By removing paragraphs (g) and (h).

The additions and revisions read as follows:

§ 305.6 Cold treatment requirements.

(a) * * * A facility will only be certified or recertified if the Administrator determines that the location of the facility is such that those Federal agencies involved in its operation and oversight have adequate resources to conduct the necessary operations at the facility, that the pest risks can be managed at that location, and that the facility meets all criteria for approval. Other agencies that have regulatory oversight and requirements must concur in writing with the establishment of the facility prior to APHIS approval. * * *

* * * * *

(2) Be capable of preventing the escape and spread of pests while regulated articles are at the facility; and

* * * * *

(b)(1) Location of facilities. Where certified cold treatment facilities are available, an approved cold treatment may be conducted for any imported regulated article either prior to shipment to the United States or in the United States. For any regulated article moved interstate from Hawaii or U.S. territories, cold treatment may be conducted either prior to movement to the mainland United States or in the mainland United States. Cold treatment facilities may be located in any State on the mainland United States. For cold treatment facilities located in the area south of 39° latitude and west of 104° longitude, the following additional conditions must be met:

(i) Prospective facility operators must submit a detailed layout of the facility site and its location to APHIS. APHIS will evaluate plant health risks based on the proposed location and layout of the facility site. APHIS will only approve a proposed facility if the Administrator determines that regulated articles can be safely transported to the facility from the port of entry or points of origin in the United States.

(ii) The government of the State in which the facility is to be located must concur in writing with the location of the facility or, if it does not concur, must provide a written explanation of concern based on pest risks. In instances where the State government does not concur with the proposed facility location, and provides a written explanation of concern based on pest risks, APHIS and the State must agree on a strategy to resolve the pest risk concerns prior to APHIS approval. If the State does not provide a written explanation of concern based on pest risks, then State concurrence will not be required before APHIS approves the facility location.

(iii) Untreated articles may not be removed from their packaging prior to treatment under any circumstances.

(iv) The facility must have contingency plans, approved by APHIS, for safely destroying or disposing of regulated articles if the facility is unable to properly treat a shipment.

(v) The facility may only treat articles approved by APHIS for treatment at the facility. Approved articles will be listed in the compliance agreement required in paragraph (f) of this section.

(vi) Arrangements for treatment must be made before the departure of a consignment from its port of entry or points of origin in the United States. APHIS and the facility must agree on all parameters, such as time, routing, and conveyance, by which the consignment will move

from the port of entry or points of origin in the United States to the treatment facility. If APHIS and the facility cannot reach agreement in advance on these parameters then no consignments may be moved to that facility until an agreement has been reached.

(vii) Regulated articles must be conveyed to the facility in a refrigerated (via motorized refrigeration equipment) conveyance at a temperature that minimizes the mobility of the pests of concern for the article.

(viii) The facility must apply all post-treatment safeguards required for certification under paragraph (a) of this section before releasing the articles.

(ix) The facility must remain locked when not in operation.

(x) The facility must maintain and provide APHIS with an updated map identifying places where horticultural or other crops are grown within 4 square miles of the facility.

Proximity of host material to the facility will necessitate trapping or other pest monitoring activities, funded by the facility, to help prevent establishment of any escaped pests of concern, as approved by APHIS; these activities will be listed in the compliance agreement required in paragraph (f) of this section. The treatment facility must have a pest management plan within the facility.

(xi) The facility must comply with any additional requirements including, but not limited to, the use of pest-proof packaging and container seals, that APHIS may require to prevent the escape of plant pests during transport to and from the cold treatment facility itself, for a particular facility based on local conditions, and for any other risk factors of concern. These activities will be listed in the compliance agreement required in paragraph (f) of this section.

(2) For articles that are moved interstate from areas quarantined for fruit flies, cold treatment facilities may be located either within or outside of the quarantined area. If the articles are treated outside the quarantined area, they must be accompanied to the facility by a limited permit issued in accordance with § 301.32-5(b) of this chapter and must be moved in accordance with any safeguards determined to be appropriate by APHIS.

* * * * *

(d) * * *

(15) An inspector will sample and cut fruit from each consignment after it has been cold treated to monitor treatment effectiveness. If a single live pest of concern in any stage of development is found, the consignment will be held until an investigation is completed and appropriate remedial actions have been implemented. If APHIS determines at any time that the safeguards contained in this section do not appear to be effective against the pests of concern, APHIS may suspend the importation of fruits from the originating country and conduct an investigation into the cause of the deficiency. APHIS may waive the sampling and cutting requirement of this paragraph, provided that the national plant protection organization of the exporting country has conducted such sampling and cutting in the exporting country as part of a biometric sampling protocol approved by APHIS.

* * * * *

(e) * * * Facilities must be located within the local commuting area for APHIS employees for inspection purposes. Facilities treating imported articles must also be located within an area over which the U.S. Department of Homeland Security is assigned authority to accept entries of merchandise, to collect duties, and to enforce the provisions of the customs and navigation laws in force.

(f) Compliance agreements. Any person who operates a facility where cold treatment is conducted for phytosanitary purposes must sign a compliance agreement with APHIS.

(1) Compliance agreements with importers and facility operators for cold treatment in the United States. If cold treatment of imported articles is conducted in the United States, both the importer and the operator of the cold treatment facility or the person who conducts the cold treatment must sign compliance agreements with APHIS. In the importer compliance agreement, the importer must agree to comply with any additional requirements found necessary by APHIS to ensure the shipment is not diverted to a destination other than an approved treatment facility and to prevent escape of plant pests from the articles to be treated during their transit from the port of first arrival to the cold treatment facility in the United States. In the facility compliance agreement, the facility operator or person conducting the cold treatment, must agree to comply with the requirements of this section and any additional requirements found necessary by APHIS to prevent the escape of any pests of concern that may be associated with the articles to be treated.

(2) Compliance agreements with cold treatment facilities outside the United States. If cold treatment of imported articles is conducted outside the United States, the operator of the cold treatment facility must sign a compliance agreement or an equivalent agreement with APHIS and the NPPO of the country in which the facility is located. In this agreement, the facility operator must agree to comply with the requirements of this section, and the NPPO of the country in which the facility is located must agree to monitor that compliance and inform the Administrator of any noncompliance.

(3) Cold treatment facilities treating articles moved interstate from Hawaii and U.S. territories. Cold treatment facilities treating articles moved interstate from Hawaii and the U.S.

territories must complete a compliance agreement with APHIS as provided in § 318.13-3(d) of this chapter.

5. Section 305.9 is amended:

a. By revising paragraph (a)(1)(ii).

b. By revising paragraph (a)(1)(vi).

The revisions read as follows:

§ 305.9 Irradiation treatment requirements.

* * * * *

(a) * * *

(1) * * *

(ii) The government of the State in which the facility is to be located must concur in writing with the location of the facility or, if it does not concur, must provide a written explanation of concern based on pest risks. In instances where the State government does not concur with the proposed facility location, and provides a written explanation of concern based on pest risks, APHIS and the State must agree on a strategy to resolve the pest risk concerns prior to APHIS approval. If the State does not provide a written explanation of concern based on pest risks, then State concurrence will not be required before APHIS approves the facility location.

* * * * *

(vi) Arrangements for treatment must be made before the departure of a consignment from its port of entry or points of origin in the United States. APHIS and the facility must agree on all parameters, such as time, routing, and conveyance, by which the consignment will move

from the port of entry or points of origin in the United States to the treatment facility. If APHIS and the facility cannot reach agreement in advance on these parameters then no consignments may be moved to that facility until an agreement has been reached.

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Done in Washington, DC, this 24th day of June 2016 .

Kevin Shea

Administrator, Animal and Plant Health Inspection Service.
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